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10/020,337	12/12/2001	Paul C. Peterson	CMI-425	1688

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EXAMINER

CHATTOPADHYAY, URMI

ART UNIT PAPER NUMBER

3738

DATE MAILED: 06/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/020,337

Applicant(s)

PETERSON ET AL.

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 December 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 3,5,6,9,10 and 16-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,7,8 and 11-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 December 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) ✓
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

This application contains claims directed to the following patentably distinct species of the claimed invention:

- 1) Figure 9 is the embodiment of the first species.
- 2) Figure 11 is the embodiment of the second species.
- 3) Figures 12 and 13 is the embodiment of the third species.
- 4) Figure 14 is the embodiment of the fourth species.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Mr. Timothy L. Scott on 2/11/03 a provisional election was made with traverse to prosecute the invention of Species 3 of Figures 12 and 13, claims 18, 19, 23-31 and 33. **Affirmation of this election must be made by applicant in replying to this Office action.**

Examiner has reviewed each of the claims and disagrees with applicant's listing of claims readable on the elected embodiment shown in Figures 12 and 13. For one, neither of the independent claims 1 and 17 was listed. Claim 17 requires that the apertures in the stent be exposed *through* the polymeric valve body, which would indicate, by definition of "through", the polymeric valve body be surrounding the stent apertures so that they can be exposed therethrough. According to the specification description of the elected embodiment shown in Figures 12 and 13, the polymeric valve body does not surround the apertures (page 7, lines 21-22), and as clearly shown in the figures, the apertures are not exposed through the valve body. This claim is readable on the non-elected embodiment of Figure 9 (Species 1). Therefore, claim 17 and claims 18-33 dependent thereon, are withdrawn from consideration. In addition, claims 3, 5, 6, 9, 10 and 16 are also withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. The claims being considered for

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examination on the merits as being readable on the elected Species 3 of Figures 12 and 13 are 1, 2, 4, 7, 8 and 11-15.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### *Drawings*

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: reference sign "XII-XII", as mentioned on page 4, line 15, is not shown in Figure 12. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: reference sign "32" in Figure 2 and reference sign "66" in Figure 14 are not mentioned in the specification. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

*Specification*

3. The specification is objected to because it is not commensurate with the figures it describes. On page 7, lines 21-22, the embodiment of Figures 12 and 13 is described as being similar to that of Figure 10 and 11. This would indicate that the polymeric material only partially covers the base, and that the polymeric material extends only to a midpoint of the base, leaving an exposed region that includes the apertures. Counter to this, on page 7, lines 23-24 the description of Figures 12 and 13 goes on to state that the stent is coated with polymeric material. This would indicate that the polymeric material covers the entire base, like that of Figure 9. In looking at Figures 12 and 13, one can see that neither of these statements accurately describes the embodiment. The polymeric material extends into the aperture, but does not enclose it, and the polymeric material does not enclose the upstream edge. Applicant must clearly and exactly describe the embodiment shown in Figures 12 and 13. For examination purposes, the examiner will interpret the elected embodiment of Figures 12 and 13 as having the polymeric valve body enclosing only a portion of the base such that the valve body does not enclose the apertures in the base.

4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: claim 2 requires that the base be circumferentially disposed *around* the valve body. This is inaccurate according to the specification and drawings, which show the base *within* the valve body. Also, claim 4 requires the portion of the base not enclosed by the polymeric valve body to include the plurality of apertures. This is not accurate according to the

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elected embodiment shown in Figures 12 and 13, which shows the polymeric valve body extending into, but not fully enclosing, the apertures. Appropriate correction is required.

5. The disclosure is objected to because of the following informalities:

- ✓ a) On page 4, line 4, it appears that "V-V" should be changed to --VI-VI--.
- ✓ b) On page 2, lines 24 and 28, it appears that "apertures or apertures" should be changed to --apertures or holes--.
- ✓ c) On page 4, line 17, a brief description of Figure 14 is required because it is missing. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

→ 7. Claim 13 recites the limitation "the suture apertures" in line 2. There is insufficient antecedent basis for this limitation in the claim. Examiner suggests changing "the suture apertures" to --the apertures--.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2, 4, 7, 8, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Reger (USPN 5,258,023 as cited in applicant's IDS).

Reger discloses a prosthetic heart valve with all the elements of claim 1. See Figure 10 for a polymeric (column 15, lines 45-53) valve body (20) having at least one leaflet having an open and closed position. See Figure 2 for stent (30) having a plurality of apertures (146) and Figure 16 for stent being coupled (column 13, lines 9-13) to the valve body. Because the valve body (20) is inserted *into* the stent (30), the apertures are disposed around and on the outside of the valve body. Therefore, because the apertures are not within the valve body, they are exposed outside of the polymeric valve body.

Claim 2, see Figure 2 for the lower, valley portions of the stent defining a base. When the valve body is inserted into the stent, the base is circumferentially disposed around the valve body. The apertures (146) penetrate the base.

Claim 4, see Figure 1 for polymeric valve body (20) enclosing only a portion of the base, the inside portion. Because the valve body is within the stent, the apertures in the base of the stent are not enclosed by the valve body.

Claim 7, see Figure 16 for sewing ring (102) circumferentially surrounding the valve body (20).

Claim 8, see Figure 7 and column 11, lines 28-32 for sewing ring (102) connected to the base at an upstream, inner side of the base.



Claims 11 and 12, see Figures 7 and 16 and column 11, lines 28-32 for sewing ring (102) circumferentially surrounding the valve body (20) and stent (30) and attached to the stent (30) by sutures (188, 190) extending through the apertures in the stent.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reger in view of Lane (USPN 5,147,391).

Reger discloses a prosthetic heart valve with all the elements of claim 1, but is silent to the additional limitation of the stent further comprising a wire connected to the upstream edge wherein the apertures are downstream from the wire. See Figure 2 for the stent comprising an upstream edge (164). Lane teaches a prosthetic heart valve wherein a wire is connected to an upstream edge of the stent in order to restrict movement to the upper portion of the frame. See column 6, lines 19-26. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Lane to modify the prosthetic heart valve of Reger by connecting a wire to an upstream edge of the of the stent in order to stiffen the lower portion of the stent and restrict movement to the upper portion of the stent. By connecting the wire to the upstream edge, the apertures will obviously be downstream from the wire.

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Claims 14 and 15, see Figures 7 and 16 and column 11, lines 28-32 for sewing ring (102) circumferentially surrounding the valve body (20) and stent (30) and attached to the stent (30) by sutures (188, 190) extending through the apertures in the stent.

12. Claims 1, 2, 4, 7, 8, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell et al. (WO 00/23006) in view of Reger.

Campbell et al. discloses a prosthetic heart valve with all the elements of claim 1, but is silent to the stent having a plurality of apertures, the apertures being exposed outside the polymeric valve body. See Figure 7 and page 3, lines 16-17 for polymeric valve body (12) having at least one leaflet (14) having an open and closed position and a stent (16) coupled to the valve body. Reger teaches a prosthetic heart valve wherein the stent (30) has a plurality of apertures (142, 144, 146) penetrating a base portion of stent (claim 2) in order to reduce the likelihood of dehiscence by reducing the mass of the stent. See Figure 2 and column 8, lines 55-60. It would have been obvious to one of ordinary skill in the art that the time of applicant's invention to look to the teachings of Reger to modify the prosthetic heart valve of Campbell et al. by including apertures penetrating a base of the stent in order to reduce the mass of the stent to reduce the likelihood of dehiscence. Because the apertures are in the base portion of the stent, they will be in the portion exposed outside of the polymeric valve body. Reger also teaches the additional limitations of claim 11 and 12, which require a sewing ring (102) to be attached to the stent (30) by sutures (188, 190) extending through the apertures in the stent. See Figure 7 and column 11, lines 28-32. It would have been obvious to one of ordinary skill in the art to look to the teachings of Reger to modify the prosthetic heart valve of Campbell et al. by attaching the

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sewing ring (54), which circumferentially surrounds the valve body and stent, to the stent by extending sutures through the apertures in the stent. Examiner contends that by extending the sutures (56) through the apertures rather than wrapping them around the stent the total length of suture used would be reduced, thereby reducing cost. In addition, the apertures could clearly indicate to the surgeon proper, equally spaced locations for suture placement to more evenly distribute the stress acting on the sutures.

Claim 4, see Figure 7 and abstract for the polymeric valve body enclosing only a portion of the base, the portion not including the plurality of apertures in the base.

Claim 7, see Figure 9 for sewing ring (54) circumferentially surrounding the valve body.

Claim 8, see Figure 10 for sewing ring being connected to the base at an upstream, inner side of the base via sutures (56).

13. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell et al. and Reger as applied to claim 1 above, and further in view of Lane.

Campbell et al., as modified by Reger, discloses a prosthetic heart valve with all the elements of claim 1, but is silent to the additional limitation of the stent further comprising a wire connected to the upstream edge wherein the apertures are downstream from the wire. See Figure 7 of Campbell et al. for the stent comprising an upstream edge. Lane teaches a prosthetic heart valve wherein a wire is connected to an upstream edge of the stent in order to restrict movement to the upper portion of the frame. See column 6, lines 19-26. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Lane to modify the prosthetic heart valve of Campbell et al. and Reger by connecting a wire to an

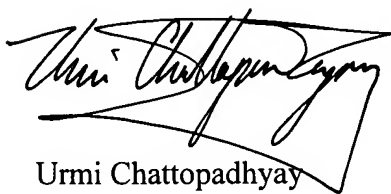
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upstream edge of the of the stent in order to stiffen the lower portion of the stent and restrict movement to the upper portion of the stent. By connecting the wire to the upstream edge, the apertures will obviously be downstream from the wire.

Claims 14 and 15, see rejections of claims 11 and 12, supra.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 305-3590. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.



Urmi Chattopadhyay

Art Unit 3738



David J. Isabella  
Primary Examiner

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May 28, 2003